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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/810,865 | 03/16/2001 | Stephen J. Brown | HERO-1-1112 | 6556 |

25315 7590 10/28/2003

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SEATTLE, WA 98104

EXAMINER

PHAN, THAI Q

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

2123

DATE MAILED: 10/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,865

Applicant(s)

BROWN, STEPHEN J. 24

Examiner

Thai Phan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to patent application S/N: 09/810,865. Claim 1 is pending.

Drawings

Acknowledgment has been made for the submission of formal drawings.

Specification

It is noted that this application appears to claim subject matter disclosed in prior Applications. It is a reminder the current status of all nonprovisional parent applications referenced should be included.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,233,539 B1, issued to Brown, Stephen. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claimed invention is directed to

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a system for simulating a disease control for predicting the effect of patient self-care actions on the disease control with feature limitations as in claim 1 of the related US patent no. 6,233,539 B1. The present claimed invention does not especially express enabling the patient to select appropriate self care actions as in claim 1 of the related patent. Practitioner in the art at the time of the invention would have found it obvious the claimed system with input means in the controller of the health care monitor system could enable patient to select appropriate actions such as selecting control parameters, parameter values, etc. related in order to monitor and control patient self-care.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's admitted prior art, in view of Hansen, Peter, US patent no. 5,394,322.

As per claim 1, the admitted prior art discloses a health care control system for simulating patient to simulate a physiological process but does not provide a mechanism to predict the effect of changes for a selected control parameter under simulation (page 2, line 21 to page 3, line 32). Such prediction mechanism under process control and simulation is however well-known in the art. In fact, Hansen teaches a controller with means for controlling and simulating process parameters

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which could be used for controlling and simulating control process such as in patient care, etc. The control system includes an input means for inputting control variable values, memory means for storing control variables and variable values scaling factors for process variables under control (col. 7, lines 22-29, 48-62, col. 11, lines 5-11, col. 32, lines 4-45, for prediction control, for example), a controller or control processor in communicating with the input means and the memory means for calculating the parameter under control, and means for displaying as claimed. Such controller operates to monitor and to adjust the process such that selected operational parameters are maintained within acceptable ranges (col. 3, lines 26-30), and with prediction control with feedback error correction (col. 32, lines 4-45, col. 37, line 65 to col. 42, line 73).

This would motivate practitioner in the art at the time of the invention was made to modify the admitted health care control system by incorporating controller with error control prediction and feedback error correction such that the controller would operate to monitor and adjust process control parameters in a manner as desire by process control and monitor as taught in Hansen, for controlling and monitoring patient healthcare process.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. US patent no. 5,680,590, issued to Parti, Michael, on Oct. 1997
2. US patent no. 5,956,501, issued to Brown, Stephen, on Sept. 1999
3. US patent no. 6,186,145 B1, issued to Brown, Stephen, on Feb. 2001

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4. US patent no. 6,233,539 B1, issued to Brown, Stephen, on May 2001

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Thai Phan whose telephone number is 703-305-3812.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3900.

Thai Phan
10/19, 2003

Thai Phan
Patent Examiner
Thai Phan
AU2123